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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-------------|----------------------|---------------------------|------------------|------|
| 10/028,450 | 10/24/2001 | Brian Craig Lee | 10010463 - 1 2047 | | |
| 7590 10/22/2003 HEWLETT-PACKARD COMPANY Intellectual Property Administration P.O. Box 272400 | | | EXAMINER JOYNES, ROBERT M | | |
| | | | | | |
| | | | Fort Collins, Co | O 80527-2400 | 1615 |
| | | | DATE MAILED: 10/22/2003 | D | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application | ı No. | Applicant(s) | | | |
|---|--|----------------|-----------|--|--|--|--|
| ř | | 10/028,450 |) | LEE ET AL. | | | |
| | Office Action Summary | Examin r | | Art Unit | | | |
| | | Robert M. J | oynes | 1615 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 17 July 2003. | | | | | | |
| 2a) 🗌 | This action is FINAL . 2b)⊠ Thi | is action is n | on-final. | | | | |
| 3) | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| | Claim(s) <u>1-20,23,24,27 and 54</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) 21,22,25,26,28-53 and 55-72 is/are withdrawn from consideration. | | | | | | |
| · | Claim(s) is/are allowed. | | | | | | |
| · | ☑ Claim(s) <u>1-20,23,24,27 and 54</u> is/are rejected. | | | | | | |
| • | Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) Notic | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2.3</u> | | | (PTO-413) Paper No(s) atent Application (PTO-152) | | | |

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DETAILED ACTION

Receipt is acknowledged of applicants' Election filed on July 17, 2003.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claims are drawn to a method of manufacturing a bioactive fluid dose on an ingestible sheet as opposed to a method of printing as stated in the Restriction requirement dated June 4, 2003. This is not found persuasive because the claims are drawn to a method wherein a fluid is used to print information on an ingestible sheet. That fluid is a bioactive fluid but the process it self is a printing process. Therefore, the restriction requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-8, 16-20, 27 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carden, Jr. et al. (US 6086942) in combination with Stewart (WO 95/01735). Carden teaches a method of depositing a radioactive fluid onto a surface of a substrate as drops from a fluid-jet print head (Col. 2,lines 42-54; Col 14, line 15 – Col. 15, line 60)). The substrate may be a flat, convex or concave sheet (Col. 4, lines 11-24). The substrate is further coated with a sealing layer or layers (Col. 8, lines 50-65). The substrate can also include the simultaneous application of colored ink and radioactive material to mark or code the outer surface of the substrate (Col. 16, lines 17-26).

Stewart teaches a method of printing on edible film or sheets (Page 9, line 19 – Page 17). The printing may include special messages, pictures, and/or drawings or other source material (Page 19, lines 1-7). The edible sheet can be used in a manner similar to normal paper thereby making available any printing machine, specifically an ink jet printer ((Page 19, lines 1-7; Page 20, lines 20-25).

Carden does not expressly teach the substrate as an edible substrate. Stewart does not expressly teach that the fluid in the ink jet cartridge is bioactive. Neither reference teaches the gradient composition recited in instant claims 9-15.

When Carden is read in view of Stewart, it would be obvious to print a bioactive fluid on an edible or ingestible sheet or substrate. Carden teaches the printing of a radioactive (bioactive) fluid onto a sheet that is later used in the body through the aid of printing equipment. The form of the sheet is not taught. Stewart teaches that edible films are known to be printed on with edible inks that convey a message or picture.

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At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to print a bioactive fluid on an edible sheet that further includes writing or a message that is achieved with edible colored ink.

One of ordinary skill in the art would have been motivated to do this to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

When Stewart is read in view of Carden, it would have been obvious to incorporate a bioactive agent in the edible fluid to be deposited on the edible sheet or film. The teachings of each reference are discussed above. Stewart teaches an edible sheet that includes printing of an edible fluid. Carden teaches bioactive fluids can be dispensed from printers onto substrates.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to print a bioactive fluid on an edible sheet that further includes writing or a message that is achieved with edible colored ink.

One of ordinary skill in the art would have been motivated to do this to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application and is delivered in a manner that achieves the best desired results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes Patent Examiner Art Unit 1615 October 20, 2003

THURMAN K. PAGE
SUPERVISORY PAPERT EXAMINER
TECHNOLOGY CENTER 1600